DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

d1711b

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (714) 798-7600

April 21, 1998

WARNING LETTER

WL-28-8

Veronica Lazarus, M.D.
Vice president
Lazarus Dermatologic Products
2001 Santa Monica Blvd., Suite 468 West
Santa Monica, CA 90404
a.k.a. Lazarus Medical Group
Lone Star Drugs
LDP, Inc.
JML Pharmaceutical, Inc.

Dear Dr. Lazarus:

An inspection of your drug distributorship located at 2001 Santa Monica Blvd., Suite 468 West, Santa Monica, CA, 90404 was conducted on July 1, 1997, by representatives from the Food and Drug Administration Los Angeles District office. A subsequent inspection of your contract manufacturer, [redacted] located at [redacted] was conducted on September 9 - 11, 1997, by representatives from the Food and Drug Administration Dallas District Office. The inspections revealed that you were marketing tretinoin (retinoic acid) products under the following labels:

1. "TRETINOIN 0.1%** Distributed by: Lone Star Drugs Beverly Hills, CA 90210"

2. "Peel Enhancer Tretinoin 0.1% manufactured for: LDP, Inc. Beverly Hills, CA 90120"

3. "Retinoic Acid 0.1% Skin Blender manufactured for: JML Pharmaceutical, Inc. Beverly Hills, CA 90210."

A search of FDA official records revealed that there is no approved application on file with the agency for the above tretinoin containing products manufactured by [redacted] for Lazarus Dermatologic Products, Inc., a.k.a. Lazarus Medical Group, Lone Star Drugs, LDP, Inc., and JML Pharmaceutical, Inc.

The article tretinoin (retinoic acid) is a drug within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act) which may not be introduced in interstate commerce under Section 505(a), since it is a "new" drug, within the meaning of Section 201(p) of the Act, and no approval of an application filed pursuant to Section 505(b) or 505(j) is effective for such a new drug and no Notice of Claimed Investigational Exemption under 505(I) is on file for such a new drug.

The continued marketing of your drug products Tretinoin .1%, Peel Enhancer Tretinoin 0.1%, and Retinoic Acid 0.1% Skin Blender without an approved new drug application (NDA), abbreviated new application (IND) constitutes a violation of Section 505(a) of the Act.

Your products Tretinoin .1%, Peel Enhancer Tretinoin 0.1%, and Retinoic Acid 0.1% Skin Blender are also misbranded within the meaning of 502(f)(1) of the Act, in that their labeling fails to bear adequate directions for the uses for which they are being offered and they are not exempt from this requirement under regulation 21 C.F.R. 201.115 since they are unapproved new drugs.

The above identification of violations is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of federal law and regulations. We request that you reply within fifteen (15) days of your receipt of this letter stating the action you will take to discontinue the marketing of these drug products. Failure to promptly correct these deviations may result in further regulatory action without further notice. The Act provides for seizure of illegal products or injunction against the manufacturer or distributor of illegal products (21 U.S.C. 332 and 334).

We request that your reply include:

1. An estimate of the amount of drugs in inventory under your control and of the amount that remains in channels of distribution outside of your control.

2. Your intention with respect to the disposition of your inventories and outstanding stocks in trade channels.

3. The date of discontinuance in the event that you have already discontinued marketing the drug products.

Your reply should be addressed to:

Mark A. Tucker, CSO
Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612 - 2445

Sincerely,

Elaine E. Messa
District Director

cc: [redacted]

State Department of Public Health
Environmental Health Services
Attention: Stuart E. Richardson, Jr.
P.O. Box 942732, MS-357
Sacramento, CA 94234 - 7320